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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,602	07/25/2003	William P. Santamore	08396.0004	9738

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,602	SANTAMORE ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The amendments to the specification are acknowledged and accepted. The objection to the specification is withdrawn.

Claim Rejections - 35 USC § 112

2. The amendment to claim 1 in response to the rejection under 35 USC 112(2) is acknowledged. The previous ground of rejection is withdrawn. However, new grounds of rejection are currently applied.
3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether method steps "c" and "d" are separate method steps, or the same single method step with a varying degree of scope. Examiner has interpreted the claim to recite a single method step, and should be amended accordingly. Additionally, "the peri-infarct or infarct region" is lacking antecedent basis and it is unclear whether "a portion of infarcted myocardial tissue" is the same as the "target region", or a new region. Examiner has interpreted it as the same region, and should be amended accordingly.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Lafontaine (US 6,343,605, hereinafter "Lafontaine").

6. In regards to claims 1 and 7, Lafontaine discloses a target intramural region, delivering a lead with an electrode (Fig. 14 and claim 3), physically modifying the mechanical properties of the region (claim 1), wherein the region is infracted myocardium (col. 12, line 32) and electrical impulses travel through the infracted region (the pulses inherently travel between the two electrode/anchors shown in Fig. 14, which is also through the infracted region).

7. In regards to claim 2, the modified properties inherently include an increase in systolic performance because Lafontaine's invention contracts at the same time as the heart wall, increasing contraction force.

8. In regards to claim 6, the modified properties include substantially no decrease in diastolic performance because Lafontaine's invention relaxes at the same time as the heart wall.

9. In regards to claim 8, the lead includes an electro-active bridge (622) spanning the infarct zone (Fig. 14).

10. In regards to claim 9, the method comprises delivering an arcuately curved lead to in the intramural space (Fig. 14, element 658; and col. 12, line 14).

11. In regards to claim 12, the lead comprises echo features (654 and 622).

Examiner is interpreting this interface as an echo feature because any interface of materials with different densities will generate an ultrasound signal.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine. Lafontaine discloses the essential features of the claimed invention except for explicitly specifying that the lead comprises radiopaque features. Lafontaine does teach of utilizing radiopaque features on the catheter for visualizing a member during the implantation procedure (col. 6, line 23). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing the lead with radiopaque features to allow visualization of the lead element, in addition to the catheter element, during the implantation procedure.

15. Claims 3, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of McVenes et al. (US 5,489,294, hereinafter "McVenes"). Lafontaine discloses the essential features of the claimed invention except for providing electrical stimulation with a pacemaker, utilizing a guidewire, or utilizing a drug-eluting surface. McVenes teaches of providing electrical stimulation to an intramural electrode with a pacemaker (col. 2, line 56) to provide stimulation in synchrony with the heart's natural rhythm, utilizing a guidewire (22) to accurately place the lead in the desired area, and utilizing a drug-eluting surface (abstract) to avoid inflammation and other morbidities associated with implanting foreign materials. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing electrical stimulation to an intramural electrode with a pacemaker to provide stimulation in synchrony with the heart's natural rhythm, utilizing a guidewire to accurately place the lead in the desired area, and

utilizing a drug-eluting surface to avoid inflammation and other morbidities associated with implanting foreign materials.

16. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Zacouto (US 5,305,745, hereinafter "Zacouto"). Lafontaine discloses the essential features of the claimed invention except for providing the stimulation with a cardioverter/defibrillator or a cardiac resynchronization device.

Zacouto teaches of providing an intramural electrode system with a cardioverter/defibrillator or a cardiac resynchronization device (a defibrillator is a cardiac resynchronization device) (col. 28, line 13) to provide stimulation that will inhibit or treat fibrillation or arrhythmia that is potentially life threatening. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing an intramural electrode system with a cardioverter/defibrillator or a cardiac resynchronization device to provide stimulation that will inhibit or treat fibrillation or arrhythmia that is potentially life threatening.

17. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Altman (RE 37,463, hereinafter "Altman"). Lafontaine discloses the essential features of the claimed invention except for utilizing a stylet to apply the electrode. Altman teaches of utilizing a stylet to apply an intramyocardial electrode to provide the stiffness necessary to push the lead during placement (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lafontaine's invention by providing a stylet to provide the stiffness necessary to push the lead during placement.

Response to Arguments

18. Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK

MWK
4/14/06

GE
GEORGE R. EVANISKO
PRIMARY EXAMINER
4/14/06